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EXAMINER	
RAE, CHARLESWORTH E	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,354	HIGASHIYAMA, MASAYO	
	Examiner	Art Unit	
	CHARLESWORTH RAE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response, filed 01/05/09, have been fully considered and made of record. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Status of the Claims

Claims 1-10 are currently pending in this application and are the subject of the Office action.

Declaration

The declaration of Masayo Higashiyama, received 01/05/09, has been considered and made of record.

The evidence submitted in support of unexpected results is not found to be sufficient to overcome the instant rejection because the exemplified preparations comprising 1.5% of bepotastine besiltate and sodium chloride 0.6% showing improved light-stability of bepotastine besilate (when compare to preparation comprising bepotastine besilate and 3.3% glucose or 3.3% manntiol) is not commensurate in scope with the instant claims. For example, instant claim 1 does not require a specific amount of bepotastine besilate or a specific "light-stabilizing effective amount" of a water-soluble metal chloride even though the study results submitted by declarant are limited to a specific concentration of bepotastine besilate of 1.5% and a concentration of sodium chloride of 0.6%. In view of the difference in scope between the exemplified

data submitted by declarant and the instant claims, one would not be able to reasonably or predicitably extrapolate the exemplified data to practice the instant claimed invention commensurate in scope with the claims.

REJECTIONS

Claim Rejections – 35 USC 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for an aqueous liquid preparation comprising, in an aqueous solution, (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid or a pharacmeutically acceptable acid addition salt thereof, and a low molecular weight water-soluble metal chloride in a light-stabilizing effective amount of 0.2% or more, does not reasonably provide enablement for preparations comprising any water-soluble metal chloride in a light-stabilizing effective amount of less than 0.2% , or any high molecular weight water-soluble metal chlorides. This is a scope of enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if its is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth in *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman* 230 USPQ 546 (BdApls 1986) at 547 the court cited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention

The invention in general relates to an aqueous liquid preparation comprising, in an aqueous solution. (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid or a pharmaeutically acceptable acid addition salt thereof, and a water-soluble metal chloride in a light-stabilizing effective amount.

Relative skill of those in the art

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. It is noted that the chemical and medical arts are generally unpredictable, requiring each embodiment to be individually assessed for chemical, pharmacologic, pharmaceutical, and clinical efficacy. The more unpredictable an area, the more specific enablement is necessary in order to satisfy the statue. (see *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)). Since the term "a light-stabilizing effective amount " is not defined by applicant, one would not be able to reasonable determine the amount of the water-soluble metal chloride that is a "light-stabilizing effective amount" without conducting extensive experimentation.

State and predcitability of the art

Jimoh (US Patent 6,369,001) teach aqueous liquid concentrate herbicidal microemulsion compositions comprising zero to a stabilizing amount of one or more water-soluble chlorides selected from hydrochloric acid, alkali metal chlorides, ammonium chloride, low molecular weight organic ammonium chlorides and quaternary ammonium chloride surfactants (abstract), wherein said stabilizing amount is directed to provide acceptable physical stability of the microemulsion (abstract; col. 6, line 5 to col..

6, line 33). Jimoh state that physical stability of the microemulsion is acceptable if no significant phase separation is evident following for at least 7 days at any temperature in the range from about 0° C to about 40° C (col. 6, lines 17-25). Jimoh state that is is preferred that the amount of **a water-soluble quaternary ammonium choride does not exceed about 6% by weight of the composition** (col. 11, lines 36-38). Jimoh teach that typical amounts of **low molecular weight organic ammonium chlorides, ammonium chloride, and alkali metal chlorides and/or hydrochloric acid are those providing abut 0.5% to about 2.5% chloride ion by weight of the composition** (col. 11, lines 60-64). Jimoh exemplifies compositions comprising ammonium chloride (cols. 17-18, Examples 4-9; col. 22, Example 22) and benzalkonium chloride (cols. 20-22, Examples 13-17 and 19). Unlike the prior art wherein the water-soluble metal chlorides are employed to enhance the physical stability of an aqueous formulation (col. 11, lines 14-64), the instant claims require water-soluble metal chlorides for their light-stabilizing properties. Since the physical stabilizing amount of the identical instantly claimed water soluble metal chlorides taught by the prior art overlaps with the instant claimed light-stabilizng effective amount of said water-soluble metal chlorides, there is serious doubt that one would be able to reasonably or predictably distinguish between the physical stabilizing effects and the light-stabilizing effects of the instant claimed water-soluble metal chlorides without resorting to extensive studies.

The breadth of the claims

The instant claims are relatively broad in scope. For example, claim 1 encompasses any and all "water-soluble metal chlorides," including high molecular

water-soluble quaternary ammonium chorides and low molecular weight chlorides as taugth by Jimoh (col. 11, lines 36-38). Further, applicant's test results show that only preparations comprising a water-soluble metal chloride in not less than 0.2 w/v% improved the stability of bepotastine besilate under light irradiation conditions (page 8, lines 6-15, including Table 1). However, claim 2 recites "wherein the metal chloride has a concentration selected from the range of a lower limit concentration of 0.15% w/v% and an upper limit concentration of 1.5 w/v%," which is less than 0.2 (see also specification, page 3, lines 2-21). Besides, as discussed above, the term "a light-stabilizing effective amount" as recited in claim 1, does not require a specific "light stabilizing amount" of a "water-soluble metal chloride" even though applicant discloses that concentrations less than 0.2% does not improve the stability of the instant claims aqueous liquid preparations. Hence, one would not be able to reasonably practice the instant claimed invention commensurate with the scope of the claims since the instant claims encompass preparations comprising water-soluble metal chloride in an amount of less than 0.2% even though applicant's test results show that concentrations less than 0.2% is devoid of light-stabilizing effect (page 8, lines 6-15, including Table 1).

The amount of direction or guidance provided and the presence or absence of working examples

The specification discloses specific formulations comprising benzalkonium chloride alone in an amount of 0.005% (specification, page 12); benzalkonium chloride 0.005% and sodium chloride in concentrations ranging from 0.79% - 0.6% (specification, pages 13-16). However, applicant states that no improvement in stability

was observed with formulations comprising less than 0.2% of a water-soluble metal chloride (page 9, lines 10-20). Since the examples are limited to low molecular metal chlorides, one would expect to reasonably extrapolate the instant exemplified data to the genus of water-soluble metal chlorides in view of the teaching of Jimoh showing that the stabilizing amount of the high molecular weight metal chloride and low molecular weight metal chlorides vary substantially from each other (e.g. a water soluble quaternary ammonium choride in amounts up to about 6% by weight, col. 11, lines 36-38; and low molecular weight organic ammonium chlorides, ammonium chloride, and alkali metal chlorides and/or hydrochloric acid are those providing about 0.5% to about 2.5% chloride ion by weight of the composition; col. 11, lines 60-64).

The quantity of experimentation necessary

In view of the uncertainty and unpredictability of the art as evidenced by the discussion of the prior art, it is reasonable to surmise that this level of uncertainty in the art would require one skilled in the art to conduct more than routine experimentation in order to practice the claimed invention commensurate with the scope of the claims.

For the reasons stated above, claims 1-10 are rejected under 35 USC 112, first paragraph, for lack of scope enablement because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 103(a) as being unpatentable over Kita et al (US Patent 6,307,052 B1; already made of record), Stevenson et al. (US Patent 4,053,628).

Kita et al. teach a benzenesulfonic acid salt and a benzoic acid salt of (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid as having excellent antihistaminic activity, anti-allergic activity, and excellent in physiochemical stability so that they are particularly suitable as a medicine (abstract; and col. 1, lines 11-21). Kita et al. teach antihistaminic compounds for use in the treatment of, for example, allergic skin disease, dermatitis, allergic rhinitis, sneeze , ..., and bronchial asthma (col. 1, lines 24-53). Kita et al. teach that the acid addition salt has little hydroscopicity and excellent physiochemical stability so that it is a particularly suitable compound as a medicine for allergic skin diseases, allergic rhinitis, sneeze, mucus, cough due to respiratory inflammation such as a cold, and bronchial asthma (column 1, lines11-54).

Kita et al. does not teach aqueous liquid preparation comprising a water-soluble metal chloride.

Stevenson et al. (US Patent 4,053,628) teach aqueous solution (e.g. eye and nasal solutions) preparations, including eye compositions comprising one or more compounds which are therapeutically useful in the eye, wherein said one or more therapeutically useful compounds include an anti-allergic agent (e.g. anti-histamines such as antazoline or diphenhydramine hydrochloride;abstract; col. 3, lines 10-16; col. 5, Examples 1-2). Stevenson et al. teach that the additional compounds may be present

at a concentration of from about 0.05 to 0.6% w/v (col. 3, lines 31-34). Stevenson et al. state that the concentration of the additives in the solution may be in the range 0.25 to 5% w/v (col. 4, lines 1-7). Stenvenson et al. teach that the preferred pH for maximum stability is from 4 to 7.5 (col. 3, lines 2-6). Stevenson et al. teach methods of treatment of conditions of the eye comprising the use of **additional therapeutically useful compounds separately from, but simultaneously with the compositions** (col. 3, lines 38-45). Stevenson et al. exemplify eye drop solution comprising sodium chloride, for example 0.56% w/v (cols. 5-6, Example 1 and 3). Stevenson et al. exemplify a preserved buffered isotonic eye-drop solution comprising sodium chloride 0.42% w/v (col. 6, Exampe 3). Stevenson et al. teach compositions for use in the treatment of eye conditions, including the ocular effects of hay fever, allerigc eyes such as spring/summer conjunctivitis (col. 4, line 59 to col. 5, line 7). Stenvenson et al. teach compositions for treating nasal conditions, including nasal rhinitis (col. 5, lines 8-13). It would have been obvious to a person of skill in the art at the time the invention was made to combine the teachings of the cited references by adding (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid) as taught by Kida et al. to an aqueous liquid composition comprising sodium chloride as taught by Stevenson et al. to treat an allergic condition (e.g. conjunctivitis or hay fever). One would have been motivated to do so because Stevenson et al. suggest aqueous solution compositions comprising one or more compounds which are therapeutically useful for topical application (e.g. eye, nose), wherein said one or more therapeutically useful compounds include an anti-allergic agent (e.g. anti-histamines; col. 3, lines 10-16) for separate

administration (col. 3, lines 38-45) to treat allergic conditions (e.g. conjunctivitis; col. 4, lines 59-66) and Kita et al. teach the identical instantly claimed compound, (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid), as being particularly suitable as a medicine for treating allergic rhinitis and sneezing (column 1, lines11-54), which is also an antihistamine drug.

Regarding claim 1, Kida et al. teach (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid).

With respect to the term "a water-soluble metal chloride in a light-stabilizing effective amount," Stevenson et al. exemplify aqueous eye drop solution comprising sodium chloride 0.56% w/v, and 0.42% (cols. 5-6, Example 1 and 3), which reads on the instant claimed limitation since sodium chloride is a water-soluble metal chloride. Since concentrations of sodium chloride of 0.56% and 0.42% as taught by the Stevenson et al. overlaps with the amount of sodium chloride disclosed by applicant as being a "light-stabilizing effective amount (specification, page 8, lines 6-15, including Table 1), one would reasonably except that the sodium chloride component of the aqueous liquid preparations encompassed by the prior art, wherein said sodium chloride is present in an amount of 02% or more (e.g. 0.56%) would also be a light-stabilizing effective amount absent objective evidence to the contrary.

Regarding the preamble, Stevension et al. teach aqueous liquid solutions (abstract; and col. 5, Example 1).

Regarding claim 2, Stevenson et al. exemplify aqueous eye drop solution comprising sodium chloride 0.56% w/v (cols. 5-6, Example 1 and 3), which reads on the

term "from the range of a lower limit concentration of 0.15% w/v% and an upper limit concentration of 1.5 w/v%.

Regarding claim 3, the above discussion of claim 2 is incorporated by reference.

Regarding claim 4, Stevenson et al. exemplify compositions wherein the therapeutically effective agent is in a concentration of ranging from 1-2% and sodium chloride in a range of 0.42 to 0.56% (cols. 5-6, Examples 1-5) such that one would reasonably expect to rely on the teaching of Stevenson et al. in preparing an aqueous liquid preparation comprising an antihistamine (e.g. (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid) in a concentration of 1-2%, which overlaps with the instant claimed amount of (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid of "0.1 to 2%, for separate administration absent objective evidence to the contrary.

Regarding claims 5-6, Kita et al. teach benzenesulfonic acid salt and a benzoic acid salt of (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid, which are acid addition salts (abstract; and col. 1, lines 11-21), which reads on the instant claims.

Regarding claim 7, Stevenson et al. teach that the preferred pH for maximum stability is from 4 to 7.5 (col. 3, lines 2-6) and the instant claims recite "a pH in the range of 4-8.5" and therefore one would reasonable expect to successfully prepare aqueous liquid formulations having a pH of 4-7.5 as encompassed by the prior art since the pH of the prior art and the instant claims overlap absent objective evidence to the contrary.

Regarding claim 8, Stevenson et al. teach eye drop (abstract; col. 5, Example 1).

Regarding caim 9, Stevenson et al. teach nasal spray solution (col. 5, Example 2), which reads on the term "nasal drop" because the nasal spray solution when sprayed is delivered (or dropped) into the nose.

Regarding claim 10, Kita et al. teach benzenesulfonic acid salt and a benzoic acid salt of (S)-4-[4-[(4-chlorophenyl)-(2-pyridyl)-methoxy]-piperidino]-butanoic acid, which are acid addition salts (abstract; and col. 1, lines 11-21) and Stevenson et al. suggest that aqueous eye solutions comprising a therapeuticially effective agent for treating an eye condition (e.g. an antihistamine) and sodium chloride in a concentration, for example, 0.5% and an antihistamine are physically stable. Since the prior art encompasses aqueous eye solutions comprising sodium chloride in an amount reads on the instant claimed amount of sodium chloride of "not less than 0.2 w/v% and not more than 0.8 w/v%" one would also expect that said amount of sodium chloride as taught by the prior art would also be an amount that is "a light-stabilizing effectice amount.

Response to applicant's arguments

Applicant's arguments with respect to the rejection under 103(a) have been considered but are moot in view of the new ground(s) of rejection. However, the merits of Kita et al. is maintained.

In response to applicant's argument that Kita does not teach the combination of said compound with any water-soluble metal chloride, it is the examiner's position that Stevenson et al. suggest the use of aqueous topical solutions comprising sodium chloride and an antihistamine agent for treating allergic conditions (e.g. conjunctivitis,

hay fever; col. 4, line 59 to col. 5, line 13) and Kita et al. teach the identical instantly claimed anthistamine compound is particularly suitable as a medicine for treating allergic rhinitis and sneezing. Since the prior art encompasses an aqueous liquid preparation comprising the identical instantly claimed antihistamine compound and sodium chloride in a concentration of, for example, 0.565% and the instant claims also require an aqueous liquid preparation comprising the identical instantly claimed antihistamine compound as taught by the prior art and a water-soluble metal chloride (e.g. sodium chloride) in a light-stabilizing effective amount that overlaps with the prior art, one would reasonably expect that the aqueous liquid preparation encompassed by the prior art would also be capable of performing the intended function such that the amount of water-soluble metal chloride (e.g. sodium chloride) is a light-stabilizing effective amount.

With respect to applicant's assertion of unexpected results, the above discussion in connection with the response to the declaration is incorporated by reference.

Thus, it would have been obvious to a person of skill in the art at the time the invention was made to create the instant claimed invention with reasonable expectation of success.

Relevant Art of Record

The below art reference made of record and relied upon is considered pertinent to applicant's invention.

Onuki et al. (US Patent Application Pub. No. 2004/0147605;already made of record) teach formulations comprising one or more antihistamine compound, including bepotastine besilate (page 2, para 0017, line 11).

Himmelstein et al. (US Patent 5,599,534; already made of record) teach pH-responsive reversible gelling compositions and liquid formulations for sustained delivery of therapeutic or diagnostic agents suitable for use as drop or spray instillable or topical drug delivery vehicles for drugs various drugs, including antihistamines and decongestants (e.g. pyrilmaine, chlorpheniramine, tetrahydrazoline, antazonline), which are particularly suitable for delivering pharmaceutical compounds to the ocular environment due to clarity and lubricating properties of the gel (col. 5, lines 32-49 and col. 8, line 51 to col. 9, line 9); flowable liquid forms of the composition are particularly useful for pharmaceutical formulations to be applied by drops (e.g. eye drops) or sprays (e.g. nasal sprays). See col. 7, lines 49-59; and col. 8, lines 29-34. Himmelstein et al. teach that the pH preferably is within the physiological range between pH 2.5 and 7.5 (col. 6, lines 35-39).

Kabra (US Patent 6,331,540) teach a method of enhancing the stability of an aqueous pharmaceutical composition containing fluoroquinolone and xantham gum and the step of adding to the composition a water-soluble calcium salt in an amount of at least 0.15 % (w/w), such that the composition is homogenous and has a turbidity rating (NTU) < = 40 at room temperature (see cols. 5-6, including Table 3 and reference claim 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau, can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16 April 2009

/C. R./ Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611